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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/442,542	11/18/1999	LONNIE D SHEA	30275/40877	6026

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EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/442,542

Applicant(s)

SHEA ET AL.

Examiner

Sumesh Kaushal Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-18, 48, 54-65, 106-108 and 118-130 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-18, 48, 54-65, 106-108 and 118-130 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/18/05 has been entered.

Claims 14-18, 48, 54-65, 106-108, 118-130 are pending and are examined in this office action.

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is **571-273-8300**.*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

Double Patenting

Claims 14-18, 48, 54-65, 106-108 and 118-130 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-53 of U.S. Pat. No. 6,642,363 in view of claims 1-35 of U.S. Pat. No. 6797738, claims 1-36 of U.S. Pat. No. 6281256, claims 1-77 of US 5763416 and claims 1-130 of U.S. Pat. No. 5942496, for the same reasons of record as set forth in the earlier office action mailed on 10/04/05

The claims of pending U.S. App. No. 09442542 are drawn to a composition comprising a porous modified alginate matrix that comprises at least one alginate chain section bonded to at least one molecule that mediates cellular interaction (i.e. RGD) and a nucleic acid segment in non-covalent association with the matrix.

The claims of USPN 6,642,363 are drawn to a modified alginate matrix comprising at least one alginate chain section, which is covalently bonded to at least one cell attachment polypeptide or RGD-polypeptide, which promotes cell adhesion and growth. However the '363 does not claim a modified alginate matrix, which is in the form of porous matrix and contains nucleic acid molecules.

The claims of USPN 6797738 and 6281256 are drawn to a porous polymer alginate material, wherein the pores are formed by gas foaming (CO₂) and leaching out the particulate material (NaCl). The claims are further drawn to the polymer material comprising a drug and/or viable cells contained within the pores of porous polymer.

The claims of USPN 5763416 and 5942496 are drawn to a composition comprising one or more nucleic acid segments in association with structural bone-compatible matrix. The claims are further drawn to a matrix composition that contains one or more genes selected from parathyroid hormone (PTH: PTH1-34) gene, a bone morphogenetic protein gene (BMP: BMP-2A, BMP-2B, BMP-3, BMP-4, BMP-5, BMP-6, BMP-7 or BMP-8 gene), a growth factor gene, a growth factor receptor gene, a cytokine gene or a chemotactic factor gene, transforming growth factor (TGF) gene, a fibroblast growth factor (FGF) gene, a granulocyte/macrophage colony stimulating factor (GM-CSF) gene, an epidermal growth factor (EGF) gene, a platelet derived growth factor (PDGF) gene, an insulin-like growth factor (IGF) gene, a latent TGF- β binding protein (LTBP) gene or a leukemia inhibitory factor (LIF) gene.

Thus it would have been obvious to one ordinary skill in the art at the time of filing to modify the RGD-linked alginate matrix of USPN 6,642,363 by introducing a pore structure in view of USPN 6797738 and 6281256 using gas foaming and/or particulate leaching. One would have been motivated to introduce porous structure in the matrix to contain drugs or viable cells in order to make a drug delivery system. It would have been further obvious to one ordinary skill in the art to substitute a drug with a nucleic

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acid molecule in view of USPN 5763416 and 5942496 which teaches a method of transferring nucleic acid segments into viable cells of an animal by contacting a matrix structure containing one or more nucleic acid of interest. One would have been motivated to do so to genetically modify the cells in order to produce recombinant proteins of interest. One would have a reasonable expectation in doing so, since modification of alginate chains to include a molecule of interest and making a porous structure by gas foaming and particulate leaching was routine in the art at the time the instant invention was made. In addition one would have a reasonable expectation of success in making and using a porous alginate matrix containing nucleic acid because such a composition had been well within the reach of one ordinary skilled in the art at the time the instant invention was made. Thus the invention as claimed is an obvious variation over cited patents of record.

Response to Arguments

The applicant argues that upon review, it is the applicants' belief that the a terminal disclaimer be filed with respect to the "primary reference" upon which the rejection is base, i.e., US Patent 6642363 which claims earliest priority of US patent application Serial Nos. 60/026362 and 60/02646. The applicant argues that if this belief is correct, the applicants respectfully request notification of the same.

However, applicant's arguments are found not persuasive. Regarding the filing a proper terminal disclaim applicant's attention is drawn again to to MPEP § 804.02 and MPEP §1490.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Therefore in view of common ownership and to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees the applicant is required to file a terminal disclaimer over US Pat. No. 6642363, 6797738, 6281256, 5763416 and 5942496


Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to **571-272-0547**. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**


SUMESH KAUSHAL
PRIMARY EXAMINER
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